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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/448,946	05/24/1995	ARJUN SINGH	P0175C2	1239
7590	09/08/2005		EXAMINER	
Genentech, Inc. 1 DNA Way SOUTH SAN FRANCISCO, CA 94080-4990			WAX, ROBERT A	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	08/448,946	SINGH, ARJUN
	Examiner	Art Unit
	Robert A. Wax	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 16 June 2005.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 47,49,50,52,58,61,63 and 64 is/are pending in the application.  
4a) Of the above claim(s) 61,63 and 64 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 47,49,50,52 and 58 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_.

**DETAILED ACTION**

***Specification***

1. Examiner notes with appreciation that the correction to the specification that was required in the previous Office action has been made.

***Claim Rejections - 35 USC § 112, First Paragraph, Enablement***

2. The amendment has overcome the previous rejections under 35 USC 112, first paragraph.

***Claim Rejections - 35 USC § 102***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claim 52 is again rejected under 35 U.S.C. 102(g) as being anticipated by the count of Interference No. 102,728.

This rejection was explained in the previous Office action.

***Claim Rejections - 35 USC § 103***

5. Claims 47, 49, 50, 52 and 58 are again rejected under 35 U.S.C. 103(a) as being unpatentable over the count of Interference No. 102,728.

This rejection was explained in the previous Office action.

***Response to Arguments***

6. Applicant's arguments filed June 16, 2005 have been fully considered but they are not persuasive. As stated above, all rejections have been overcome except those under 35 USC 102 and 103 as based upon the count of Interference No. 102,728.

Applicants argue that, since the instant claims are not limited to the production of mature proteins and further that, as a result of the differences in claim scope between the claims involved in the interference, and those of the present application, a determination of priority with respect to the presently claimed subject matter was never undertaken.

Applicants continue with the statements that the present claims encompass the production of the previously-discussed Glu-Ala-containing proteins, and thus, Singh's October 1, 1982 production of incompletely processed heterologous protein is a reduction to practice which antedates the Brake '008 patent, and would have resulted in Singh prevailing in an interference directed to the presently claimed subject matter. Moreover, under the two-way obviousness test, the present claims could not have been added to Interference 102,728. Therefore, there should be no estoppel from Interference 102,728 that applies against the present claims.

Examiner agrees with the allegation that a determination of priority with respect to the presently claimed subject matter was never undertaken but must respectfully disagree that the doctrine of interference estoppel does not apply.

The scope of estoppel arising out of an interference is defined by 37 CFR § 1.658(c). That rule reads:

"A judgment in an interference settles all issues which (1) were raised and decided in the interference, (2) could have been properly raised and decided in the interference by a motion under § 1.633 (a) through (d) and (f) through (j) or § 1.634, and (3) could have been properly raised and decided in an additional interference with a motion under § 1.633(e). A losing party who could have properly moved, but failed to move, under § 1.633 or 1.634, shall be estopped to take ex parte or inter partes action in the Patent and Trademark Office after the interference which is inconsistent with that party's failure to properly move, except that a losing party shall not be estopped with respect to any claims which correspond, or properly could have corresponded, to a count as to which that party was awarded a favorable judgment." 37 CFR § 1.658(c).

The facts of this case fall squarely within the terms of Rule 658(c). Under the rule, a judgment in an interference settles, among other things, all issues which could have been properly raised and decided in an additional interference under 37 CFR § 1.633(e). Notwithstanding the two-way obviousness test, the issue of priority of invention with respect to the more generic invention, that is, expression of mature and immature proteins, defined by the instant claims, is an issue that could have been raised and decided in an additional interference if Applicant had filed the proper preliminary motions during Interference 102,728, that is, an additional count for the interference representing the generic invention.

Under Rule 658(c), a losing party who could have properly moved for an additional interference under Rule 633(e), but failed to do so, is estopped from taking action in the USPTO after the interference that is inconsistent with the party's failure to properly move. Note that the exception set out in Rule 658(c) does not apply here, since Applicant was not awarded a favorable judgment with respect to any count in Interference 102,728.

Applicant's action in the instant case – asserting claims to the expression of both mature and immature protein – is inconsistent with Applicant's failure to properly move for declaration of an additional interference during Interference 102,728. Thus, the estoppel defined by Rule 658(c) applies to the present case.

The Notice of Final Rule, Patent Interference Practice, 49 Fed. Reg. 48416 (Dec. 12, 1984), reprinted in 1050 Off. Gaz. Pat. Office 385 (Jan. 29, 1985), provided various examples of how estoppel under Rule 658(c) applies. Example 29 is especially relevant:

Example 29. Applicant AQ discloses and claims invention "F." Applicant AR discloses and claims separate patentable inventions "F" and "G." The assignee of applicant AQ also owns an application AS which discloses and claims invention "G." An interference is declared between applicant AQ and applicant AR. The sole count is directed to invention F. No motion is filed by applicant AQ or its assignee to declare an additional interference between applicant AR and applicant AS with a count to invention G. A judgment as to all of AR's claims corresponding to the sole count is awarded to applicant AR. Applicant AS and the assignee would be estopped to obtain a patent containing claims to invention G, because applicant AR and the assignee failed to move to declare an additional interference with a count to invention G.

49 Fed. Reg. at 48427.

The example accurately reflects the relevant facts of this case:

- Applicant Brake (Applicant AQ) disclosed and claimed recombinant production of mature protein (invention F).
- Applicant Singh disclosed and claimed the same method of expressing protein, and also disclosed of immature protein containing Glu-Ala (invention G).
- An interference was declared between Brake and Singh. The sole count in the interference was directed to expression of mature protein using the alpha factor promoter (invention F).
- No preliminary motion was filed by applicant Brake or its assignee to declare an additional interference with a count to expression of immature protein (invention G).
- A judgment as to all of Brake's claims corresponding to the sole count was awarded to Brake.

Therefore, applicant Singh and the assignee are estopped to obtain a patent containing claims to expression of immature protein, because applicant Singh and the assignee failed to move to declare an additional interference with a count to that product.

The above example differs from the facts of the case only by the absence of another application and, thus, no invention AS. Interference estoppel under § 1.658(c) is designed to implement the PTO's intent to have as many issues resolved as possible in a single inter partes proceeding." 49 Fed. Reg. at 48446 (responding to comments that had suggested a "less restricted 'interference estoppel'"). Applying Rule 658(c)'s estoppel provision in this case is therefore consistent with the purpose of the rule.

The controlling case law appears to be In re Kroekel, 803 F.2d 705, 709, 231 USPQ 640, 643 (Fed. Cir. 1986) which states, in part, "[e]stoppel should be decided on the facts of each case with reference to principles of equity."

Applicant was in a better position than Brake to recognize the existence of commonly disclosed subject matter, and to take action to put it in issue during the

interference. At the time preliminary motions were filed in Interference 102,728, Applicant had full knowledge of the disclosure of his application and, therefore, Applicant could have seen that priority of invention with respect to the generic subject matter was an issue to be raised during Interference 102,728. By contrast, there is no evidence in the record to show that, at the time preliminary motions were due, Brake knew of the existence of Applicant's copending application.

The time to have raised and decided the issue of priority of invention with respect to the generic invention now claimed was during Interference 102,728. Since the Brake application involved in that interference issued as U.S. Patent 4,870,008 on September 26, 1989, an additional interference cannot now be held to determine the issue. In addition, even if another interference were possible, it would be unfair to now subject Brake to another interference proceeding in order to decide an issue that properly could have been raised and decided in the first interference. Cf. Ex parte Kimura, 55 USPQ2d 1537, 1547 (Bd. Pat. App. Int. 2000): "Rule 658(c) benefits the winning party in an interference. The winning party knows that its losing opponent will not be able to claim subject matter which the losing opponent could have placed in issue in the interference."

Thus, the rejections of record under 35 USC 102 and 103 must be maintained

***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert A. Wax  
Primary Examiner  
Art Unit 1653

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